EXHIBIT 48

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re:
Bair Hugger Forced Air Warming
Products Liability Litigation

This Document Relates To:

All Actions

MDL No.
15-2666 (JNE/FLM)

VIDEOTAPED DEPOSITION

OF

CHRISTOPHER NACHTSHEIM

Minneapolis, Minnesota

Tuesday, November 29, 2016

Reported by:
Amy L. Larson, RPR
Job No. 113495

the question.

THE WITNESS: That would be the next best alternative.

BY MR. SACCHET:

Q. Why is that?

A. Here what we're doing with the -- with the randomized -- with a clinical trial is that we're going to actually put both -- both types of blankets in practice and we can look at -- look directly at infection rates that result from the two different conditions, and that's the -- that's the clinical study. If you're looking at -- if you want to know about infections, I think you're limited to looking at observational studies such as -- such as the one that we report on.

We did -- we did experimental studies on bubbles, but we can't do experimental studies on infections without -- without resorting to a clinical trial of some kind.

So I think that, yeah, I think you probably -- if you want to look at infections, I think you're -- I think you're

probably limited to observational data.

Q. Isn't it true that a well-designed observational study can render results extremely similar to a properly conducted randomized trial --

MS. GARCIA: Object --

BY MR. SACCHET:

Q. -- on the same subject matter?

MS. GARCIA: Object to the form of the question.

THE WITNESS: I think that can happen, but I don't believe that the level of proof reaches the same -- I don't think that the proof reaches the same level of rigor. There's just always that chance in observational studies that -- I mean, I think there's a greater chance that something -- a confounding factor might be present, something you just hadn't thought of.

BY MR. SACCHET:

Q. But it is possible that if statistical significance is found based on observational data, that that significance may be replicated in a randomized control trial?

A. Yes.

Q. So the observational data that is presented in the McGovern study is certainly valuable, is it not?

MS. GARCIA: Object to the form of the question.

THE WITNESS: I think it's valuable.

BY MR. SACCHET:

Q. That's why you published the observational data, correct?

A. Yes.

Q. You were previously asked about potentially confounding factors with respect to the observational data that was presented in the McGovern study, correct?

A. Correct.

Q. And some of those potentially confounding factors dealt with infection control measures, correct?

A. Correct.

Q. If we could turn to page 1540 of Exhibit 4, the McGovern study.

A. (Complies.)

Q. I want to make sure that we are on the same page with respect to the change that occurred as to the antibiotic regime. Would you agree that an antibiotic called Gentamycin was applied during the forced-air warming period from July 1st, 2008, to the end of February 2009? It's about halfway down the paragraph.

A. I see it. From July 2008 to February 2009 a single dose of Gentamicin 4.5 was given at -- at induction.

Q. Whereas, a combination of Gentamycin and Teicoplanin -- and I'd be surprised if any of us know how to pronounce it, but that's how I'm going to say it -- was applied during the end of the forced-air warming period and throughout the entire conductive fabric warming period, which would namely be March 1st, 2009, until January 2011, correct?

MS. GARCIA: Can you please point to where you're reading from?

MR. SACCHET: So I am interpreting what's said in this paragraph and based on what's presented in Figure 7 so --

MS. GARCIA: Okay. Then I'll

p-value was a statistically significant value, correct?
A. Yes, correct.
Q. So there were fewer wound complications as a result of the use of a low weight molecular heparin --
A. Correct.
Q. -- compared to Rivaroxaban, correct?
A. Yeah, correct.
MS. GARCIA: Object to the form of the question.
BY MR. SACCHET:
Q. However, the study notes that rates for RTT, which we established to be a return to theater for --
A. Uh-huh.
Q. -- infections, were not significantly different; do you see that?
A. Correct. Yes, I do.
Q. Assuming the truth -- well, let me back up.
Would you also agree that the McGovern study, Exhibit --
MS. GARCIA: Four.
BY MR. SACCHET:

Q. -- 4, evaluated joint infections?
A. Yes.
Q. It did not evaluate wound complications, did it?
A. Correct, it did not.
Q. Assuming the truth of this study, would you ultimately agree that the change in protocol from Tinzaparin, which is an LMWH, to Xarelto, otherwise known as Rivaroxaban, and then back to Tinzaparin, did not significantly affect the infection rate?
MS. GARCIA: Object to the form of the question, to lack of foundation, and it's an incomplete hypothetical.
THE WITNESS: Assuming the study was carefully done and generalizable, yes.
BY MR. SACCHET:
Q. And assuming the study was well done and generalizable, would you agree that the change in thromboprophylaxis noted in the McGovern study, Exhibit 4, did not confound the infection rates?
MS. GARCIA: Object to the form of the question.

THE WITNESS: Assuming -- yes.
BY MR. SACCHET:
Q. And would you also conclude that, assuming the truth of this study, it would be improper to deselect all of the patients who received Xarelto, otherwise known as Rivaroxaban, from the patient population if the thromboprophylaxis was not a confounding variable?
MS. GARCIA: Object to the form of the question.
THE WITNESS: It doesn't seem justified in -- on the basis of these results.
BY MR. SACCHET:
Q. And, in fact, when the coauthors of the McGovern study were in the process of publication, are you aware that at numerous times they sought to collect additional data in support of the study?
A. I was not aware of that. I knew that -- I knew that they sought to run this study out in time.
Q. Are you aware that when Mr. Albrecht and

Dr. Reed collected additional data that went beyond January 2011 in the conductive fabric warming population, that the data still showed a significant decrease in infections when conductive fabric warming was used?
A. I'm aware of that.
Q. Assuming that --
MS. GARCIA: Can we take a break shortly?
MR. SACCHET: Yeah, give me two minutes.
BY MR. SACCHET:
Q. Assuming that neither the antibiotic nor the thromboprophylaxis protocol required control because they were not confounding factors as we discussed, you would be confident in the results of the observational study presented in the McGovern data?
MS. GARCIA: Object to the form of the question.
THE WITNESS: I'm confident that those weren't confounding factors, that those studies are well done. It doesn't rule out the potential for other confounding factors.

NACHTSHEIM

MR. SACCHET: Fair enough.

BY MR. SACCHET:

Q. And you continue to stand by the results of the observational studies --

A. Yes.

Q. -- in the McGovern publication?

A. I do.

MR. SACCHET: Let's take a break.

THE VIDEOGRAPHER: We're going off the record at 5:07 p.m.

(Whereupon, a brief recess was taken.)

THE VIDEOGRAPHER: This is video number 6 in the deposition of Christopher Nachtsheim. Today is November 29th, 2016. We're going back on the record at 5:18 p.m.

BY MR. SACCHET:

Q. Professor Nachtsheim, if we could turn to Exhibit 5, which is the Belani study.

A. I have it.

Q. Great. And as to this study, your role was to exclusively review the statistical portion of this study, correct?

A. Correct.

NACHTSHEIM

Q. You had no involvement in the setup of the experiment?

A. I did not.

Q. You had no role in the execution of the physical experiment?

A. I did not.

Q. You had seen, whether by video or in person, disruption of laminar flow caused by the Bair Hugger before, correct?

A. I had, yes.

MS. GARCIA: I'm sorry, can I hear that question again? I was thinking and I did not hear the question.

MR. SACCHET: Can you -- do you mind repeating it.

(Whereupon, the last question was read by the court reporter.)

MS. GARCIA: Object to the form of the question, asked and answered.

BY MR. SACCHET:

Q. So you were familiar with the possibility, based on your personal experience, that the Bair Hugger could disrupt laminar airflow, correct?

NACHTSHEIM

MS. GARCIA: Object to the form of the question, misstates the record and lack of foundation.

THE WITNESS: Correct.

BY MR. SACCHET:

Q. If we could turn to the third page of the study.

A. (Complies.) 408?

Q. Yes. Do you see the header entitled, "Statistical Analysis"?

A. I do.

Q. And it reads, "A Poisson regression model for overdispersed data was fit having the sum of bubble counts for each experimental run," paren, "ten pictures," end parens, "as the response, and the factors identified in the experimental design as predictors plus an interaction term." Do you see that?

A. I do, yes.

Q. Did you determine that a Poisson regression was the most appropriate statistical model to employ because you were dealing with counts data -- or data counts?

A. Yes.

NACHTSHEIM

MS. GARCIA: Object to the form of the question, previously asked and answered.

BY MR. SACCHET:

Q. And that Poisson regression was a better model to use than, let's say, an ANOVA model?

MS. GARCIA: Object to the form of the question, previously asked and answered.

THE WITNESS: Yes.

BY MR. SACCHET:

Q. And if we could just turn our attention one paragraph above that, it says, "For the experimental design, a replicated and equals to 2 by 3 full factorial design was used to assess changes in bubble counts over the surgical site," correct?

A. Correct.

Q. And what were the factors?

A. So the first factor is the anesthesia screen, low grade/high grade, those are the two levels, and then there were three patient-warming devices, conductive fabric, forced-air or no warming device, and that would -- that was considered a control.

Q. Does Figure 3, directly above that paragraph,